510(k) SUMMARY – Fox PTA Catheter

Submitter Name:	Jomed AG
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Date Prepared:	15 March 2002
Device Trade Name:	Fox PTA Catheter
Device Common Name:	Peripheral Transluminal Angioplasty Catheter
Classification Name:	21 CFR 870.1250 Percutaneous Catheter
Predicate Devices:	• Jomed Fox PTA Catheter, K010838 • Guidant VIATRAC PTA Catheter, K000101 • NuMED Ghost II PTA Catheter, K003972
Device Description:	The JOSTENT® Fox PTA Catheter consists of a double lumen catheter with a balloon located at the distal tip. The catheter will be available with balloon diameters of 3.0 - 12.0 mm and balloon lengths of 20 - 80 mm. The catheter will be available in lengths of 75 and 135 cm. The catheter is compatible with 0.035" diameter guidewires.
Intended Use:	The Fox PTA Catheter is intended for dilatation of lesions in the femoral, renal, iliac, popliteal, peroneal, and profunda arteries and native or synthetic arteriovenous dialysis fistulae.
Device Technological	The Fox PTA Catheter is made of similar materials, is

Characteristics and Comparison to Predicate Device(s):	available in similar diameters and lengths, has a similar design, and the same indications for use as the predicate devices and other currently marketed PTA Catheters.
Performance Data:	Bench, biocompatibility, and design control activities demonstrate the safety and effectiveness of the Fox PTA Catheter.
Conclusion:	The Fox PTA Catheter is substantially equivalent to the claimed predicate devices and other currently marketed PTA Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 11 2002

Mr. Glenn N. Byrd, MBA, RAC
Director, Regulatory Affairs
Eminent Research Systems, Inc
1700 Rockville Pike, Suite 400
Rockville, MD 20852

Re: K020854
JoMed Fox PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: 74 LIT
Dated: April 2, 2002
Received: April 2, 2002

Dear Mr. Byrd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020854

Device Name: Fox PTA Catheter

Indications for Use:

The Fox PTA Catheter is intended for dilatation of lesions in the femoral, renal, iliac, popliteal, peroneal, and profunda arteries and native or synthetic arteriovenous dialysis fistulae.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K020854

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)